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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,732

09/30/2004

Clare J. Watkins

BJS-620-334

9948

23117

7590

05/05/2008

NIXON & VANDERHYE, PC

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,732	Applicant(s) WATKINS ET AL.	
	Examiner Erich A. Leeser	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-84, 87-116 and 119-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-84, 87-116 and 119-173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>January 18, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant cancelled claims 1-79, 85-86, and 117-118. Claims 80-84, 87-116 and 119-173 are pending and under examination.

Information Disclosure Statement

The references cited in the IDS, dated January 18, 2008, are made of record.

Claim Rejections - 35 USC § 112

Examiner previously rejected claims 80-173 because the specification failed to reasonably provide enablement for making a prodrug of the claimed compounds. Based on Applicant's claim amendments, this rejection based upon prodrugs has been overcome.

Examiner previously rejected claims 80-173 because the specification does not reasonably provide enablement for making solvates of the claimed compounds. Applicant argues that the specification sufficiently enables making solvates of the claimed compounds and a court would decide that the Wands factors favor enablement. Examiner finds this argument unpersuasive and therefore maintains the enablement rejection with regards to solvates.

Examiner previously rejected claims 169-173 as failing to comply with the enablement requirement because the specification does not enable the instant compounds to inhibit HDAC in a cell, treat a condition mediated by HDAC, a proliferative condition, cancer or psoriasis with a therapeutically-effective amount of a compound of claim 80 or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Applicant argues that the "cell based data and in vivo data on pages 190-193 of the specification" "demonstrates the making and using of the claimed invention to, for example,

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inhibit HDAC in a cell, treat a condition mediated by HDAC, treat a proliferative condition, and treat cancer." Examiner finds this argument unpersuasive and therefore maintains the enablement rejection.

Examiner previously rejected claims 80, 118 and 142 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Based on Applicant's claim amendments and cancellations, the rejection has been overcome.

Claim Rejections - 35 USC § 102

Examiner previously rejected claims 80-81, 85, 98, 102, 116-117, 138-141, 145-146, 163-164 and 168 are under 35 USC 102(b) as being anticipated by Bedell, et al., U.S. Patent No. 7,115,632; McDonald, et al., U.S. Patent No. 6,696,449; and McDonald, et al., U.S. Patent No. 6,683,078. Based on Applicant's claim amendment of removing C₅₋₂₀arylene from the definition of Q², this rejection has been overcome.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624

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Patent Examiner, Art Unit 1624

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